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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/783,777	11/17/97	JARRELL	Q 0778377

16N2/13002  
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EXAMINER	
DEPARTMENT OF COMMERCE	
ART UNIT	PAPER NUMBER

1611 3

DATE MAILED: 10/07/97

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

#### OFFICE ACTION SUMMARY

- Responsive to communication(s) filed on \_\_\_\_\_
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- Claim(s) 1 - 20 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- Claim(s) 20 is/are allowed.
- Claim(s) 1, 12, 17, 18, 19 and 13 - 15 is/are rejected.
- Claim(s) 2-11, 16 is/are objected to.
- Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - All  Some\*  None of the CERTIFIED copies of the priority documents have been
    - received.
    - received in Application No. (Series Code/Serial Number) \_\_\_\_\_
    - received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received:

- Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- Notice of Reference Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

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## DETAILED ACTION

### ***Claim Objections***

1. Claims 1 and 19 are objected to because of the following informalities: in line 6, Applicant has omitted the number of carbon atoms, which the Examiner believes should be --7--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. Claims 13, 14, 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 13, substituent "Q" is not defined. Accordingly there is no antecedent basis for substituent "Q" in claims 14 and 15.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

5. Claims 1, 12, 17, 18, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rivier et al., 5,506,207 in view of Hoeger et al. 5,296,468.

Rivier et al. teach Applicant's claimed GNRH antagonists and pharmaceutical compositions thereof, wherein said antagonists are useful for inhibiting the secretion of gonadotropins in mammals. Specifically, the peptides at position 5 and 6 contains Aph which may be substituted with an acyl group, i.e. formyl or atz (3-amino 1,2,4 triazole). Please refer to col. 5, lines 10-40 ; col. 7, lines 20-30; col. 18, line 66 to col. 19 line 30; claim 15.

Rivier does not disclose that Aph may be substituted with C(O)NHR, i.e carbamoyl. For this feature the Examiner refers to Hoeger et al., which teaches similar GNRH antagonists wherein at positions 5 and 6 the Aph is substituted with C(O)NHR<sub>2</sub>, wherein R<sub>2</sub>= H or alkyl group. Please refer to col. 3, lines 3-45; col. 10, lines 9-35. Rivier et al. also disclose pharmaceutical compositions of said peptide antagonists useful for inhibition or control of gonadal activity. Please see col. 28, lines 35-43.

It would have been obvious to one of ordinary skill in the art to modify the peptides of Rivier to additionally substitute Aph at positions 5 and 6 with C(O)NHR<sub>2</sub> because both Rivier and Hoeger have established that such modifications are known in the art and as Rivier states at col. 20, lines 1-4, such modifications , "known in the art", would not be expected to alter the effectiveness of the peptides as GNRH antagonists.

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6. Claims 1, 12, 17, 18, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rivier in view of Hoeger as applied to claims 1, 12, 17, 18, 19 above, and further in view of Jiang et al.

Rivier and Hoeger as applied above.

Rivier and Hoeger do not teach Amf(4-aminomethyl Phe) as an amino acid for positions 5 and 6, Yet, Jiang discloses GNRH antagonists which contain Amf(4-aminomethyl Phe) at positions 5 and 6. Please see the abstract.

It would have been obvious to one of ordinary skill in the art to modify the peptides of Rivier and Hoeger to additionally substitute Amf at positions 5 and 6 because Rivier, Hoeger and Jiang have established that such modifications are known in the art and as Rivier states at col. 20, lines 1-4, such modifications or substitutions , "known in the art", would not be expected to alter the effectiveness of the peptides as GNRH antagonists. Finally, Amf appears to be a homologue of Aph in that a methyl group is inserted between the benzene ring and the amino group. It is held that "compounds which are homologues (compounds differing regularly by the successive addition of the same chemical group, e.g. by -CH<sub>2</sub>- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties". In re Wilder 563 F.2d 457, 195 USPQ 426 (CCPA 1977). Also please refer to MPEP 2144.09, page 2100-123, first column, second full paragraph.

7. Claims 2-11,16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Claim 20 is free from the prior art because the prior art does not teach substitution of Aph or Amf at positions 5 and 6 with L/D Hor or D/L imz.

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**Conclusion**

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Yanaihara et al., Biochem. Biophys. Res. Commun., (1973), 51(1), 165-73.

Haviv et al. 5,491,217.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on (703) 308-0254. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM

Sep. 26, 1997

Cecilia J. Tsang  
Supervisory Patent Examiner  
Group 1800